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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,671	09/07/2006	Michael Martin	20674-0008US1	8699

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
03/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/598,671	MARTIN, MICHAEL	
	Examiner	Art Unit	
	John Pak	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-10, 12-14, 16-17 (in part), drawn to method of reducing severity of inflammation in a subject by administering to the subject an effective amount of lithium chloride.

II. Claims 1-9, 11-16, 18 (in part), drawn to method of reducing severity of inflammation in a subject by administering to the subject an effective amount of SB216763.

III. Claims 1-9, 13 and 15-16 (in part), drawn to method of reducing severity of inflammation in a subject by administering to the subject an effective amount of a substance that is not lithium chloride or SB216763.

IV. Claims 19-21, 23 (in part), drawn to method of reducing the severity of inflammation in a tissue culture biological system comprising administering an agent that inhibits glycogen synthase kinase 3.

V. Claims 19-20, 22-23 (in part), drawn to method of reducing the severity of inflammation in an organic culture biological system comprising administering an agent that inhibits glycogen synthase kinase 3.

VI. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with systemic lupus erythematosus.

VII. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with Hashimoto's disease.

VIII. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with rheumatoid arthritis.

IX. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with graft-versus-host disease.

X. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with Sjögren's syndrome.

XI. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with pernicious anemia.

XII. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with Addison disease.

XIII. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with scleroderma.

XIV. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with Goodpasture's syndrome.

XV. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with Crohn's disease, inflammatory bowel disease or ulcerative colitis.

XVI. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with autoimmune hemolytic anemia.

XVII. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that

inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with myasthenia gravis.

XVIII. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with multiple sclerosis.

XIX. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with Basedow's disease.

XX. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with thrombopenia purpura.

XXI. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with insulin-dependent diabetes mellitus.

XXII. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with allergy.

XXIII. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with asthma.

XXIV. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with cancer.

XXV. Claims 24-26 (in part), drawn to method of reducing the severity of inflammation in a subject comprising administering to the subject an effective amount of an agent that inhibits phosphorylation of glycogen syntase kinase 3, wherein the subject has inflammation associated with cardiomyopathy.

XXVI. Claims 27-29, drawn to method of reducing the risk of inflammation in a recipient of an implantation or transplantation comprising contacting the implant or transplant with an agent that inhibits glycogen synthase kinase 3 activity or modulates phosphorylation of glycogen synthase kinase 3 activity.

The inventions listed as Groups I to XXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The claims in this application encompass a broad scope of therapeutic treatment. Unity of invention exists only when there is a technical relationship among the claimed invention involving one or more of the same or corresponding special technical features. The expression "special technical feature" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. In the instant case, there are numerous prior art teachings that establish presumption of lack of novelty or inventive step in the independent claims, so that there is no technical relationship left over the prior art among the claimed inventions, leaving the various inventions without a single general inventive concept.

For example, WO 00/38675 (SMITHKLINE BEECHAM PLC, published 06 July 2000) discloses treatment and prophylaxis of diabetes and conditions associated with diabetes or cancer by administering SB 216763 (see for example, claim 5 wherein R is hydrogen, R^2 is hydrogen, R^3 is Me, R^4 is 2,4-di-Cl, U.S. 4,386,072 (HORROBIN et al.) teaches administering a lithium salt for treatment and prophylaxis of disorders of inflammation (see claim 1). MEDLINE Abstract 83257030 (available on STN Online on

19 March 1999) teaches lithium chloride to reduce the incidence of infection in cancer patients. These documents were cited and supplied in the International Application.

Therefore, there is no same or corresponding technical feature that defines a contribution which each of the inventions, considered as a whole, makes over the prior art. Consequently, the 26 inventions as set forth above are not so linked together as to form a single general inventive concept.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/
Primary Examiner, Art Unit 1616